TITLE 25. HEALTH SERVICES
Part 1. TEXAS DEPARTMENT OF HEALTH
Chapter 229. Food and Drug
Subchapter X. Licensure **[Licensing]** of Device Distributors and Manufacturers
Amendments ''229.432 - 229.433, 229.441, 229.443

Proposed Preamble

The Texas Department of Health (department) proposes amendments to ''229.432 - 229.436, 229.439, 229.441, and 229.443, concerning the licensure of device distributors and manufacturers. Specifically, the sections cover applicable laws and regulations; definitions; exemptions; licensure requirements; licensure procedures; licensure fees; minimum standards for licensure; and enforcement and penalties. Amended '229.432 will eliminate references to the U.S. Food and Drug Administration=s (FDA) medical device distributor reporting regulation and to the FDA=s requirements for cigarettes and smokeless tobacco, based upon the repeal of those provisions by the FDA. Amended '229.433 will add new definitions for Aflea market@, Apractitioner@, and Aprescription device@ to provide clarification of statutory intent. Amended '229.434 will clarify licensure exemptions with respect to Health and Safety Code, Chapter 483. Amended '229.435 will clarify requirements for amending a license and for licensing distributors and manufacturers of combination products. The new language concerning combination products will reflect certain provisions added as a result of Senate Bill 1236, passed by the 76th Texas Legislature. Amended '229.436 revises references for licensure contacts and updates licensing procedures. Amended '229.439 updates referenced citations for licensure fee exemptions. Amended '229.441 will clarify existing requirements for prescription devices and the sale of contact lenses at flea markets. The new language concerning the sale of contact lenses at flea markets will reference provisions added by House Bill 749, passed by the 76th Texas Legislature. Amended '229.443 will clarify requirements dealing with access to and retention of records and will update the enforcement provisions related to adulterated and misbranded devices.

Cynthia T. Culmo, R.Ph., Director, Drugs and Medical Devices Division, has determined that for the first five-year period the sections are in effect, there will be no fiscal implications to state or local government as a result of enforcing or administering the sections as proposed because the licensing requirements are not being substantially changed.

Ms. Culmo has also determined that for each year of the first five years the sections as proposed are in effect, the public benefit will be clarification of minimum standards for licensure of device distributors and manufacturers. There will be no adverse economic effect on micro-businesses and/or small businesses and persons who may be required to comply with these sections as proposed. The finding of no adverse economic effect on micro-businesses and/or small businesses is based on the intent of the proposed sections to clarify existing licensing requirements and the determination

that no changes to existing licensure fee schedules will occur. There will be no impact on local employment.

Comments on the proposed amendments may be submitted to Thomas E. Brinck, Drugs and Medical Devices Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756, (512) 719-0237. Comments will be accepted for 30 days from the date of publication of this proposal in the *Texas Register*.

The amendments are proposed under the Health and Safety Code, '431.241, which provides the department with the authority to adopt necessary regulations pursuant to the enforcement of Chapter 431; and '12.001, which provides the Texas Board of Health (board) with the authority to adopt rules for the performance of every duty imposed by law on the board, the department, and the commissioner of health.

The amendments affect Health and Safety Code, Chapter 431.

Legend: (Proposed amendment)
Single Underline = Proposed new language
[Bold Print and Brackets] = Current language proposed for deletion
Regular Print = Current language
(No change.) = No changes are being considered for the designated subdivision

'229.432. Applicable Laws and Regulations.

(a) The Texas Department of Health (department) adopts by reference the following laws and regulations:

(1) - (3) (No change.)

[(4) 21 CFR, Part 804, Medical Device Distributor Reporting, as amended;]

(4) **[(5)]** 21 CFR, Part 807, Establishment Registration and Device Listing for Manufacturers and Initial Importers **[Distributors]** of Devices, as amended;

(5) **[(6)]** 21 CFR, Part 814, Premarket Approval of Medical Devices, as amended;

(6) **[(7)]** 21 CFR, Part 820, Quality System Regulation, as amended;

[(8) 21 CFR, Part 897, Cigarettes and Smokeless Tobacco, as amended;] and

(7) **[(9)]** 21 CFR, Subchapter J - Radiological Health, as amended.

(b) - (c) (No change.)

'229.433. Definitions. The following words and terms, when used in these sections, shall have the following meanings, unless the context clearly indicates otherwise.

(1) - (11) (No change.)

(12) Flea market - A location at which booths or similar spaces are rented or otherwise made available temporarily to two or more persons and at which the persons offer tangible personal property for sale.

(13) **[(12)]** Health authority - A physician designated to administer state and local laws relating to public health.

(14) **[(13)]** Importer - Any person who initially distributes a device imported into the United States.

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(15) **[(14)]** Ionizing radiation - Any electromagnetic or particulate radiation capable of producing ions, directly or indirectly, in its passage through matter. Ionizing radiation includes gamma rays and x-rays, alpha and beta particles, high speed electrons, neutrons, and other nuclear particles.

(16) **[(15)]** Labeling - All labels and other written, printed, or graphic matter:

(A) upon any article or any of its containers or wrappers; or

(B) accompanying such article.

(17) **[(16)]** Manufacture - The making by chemical, physical, biological, or other procedures of any article that meets the definition of device. The term includes the following activities:

(A) repackaging or otherwise changing the container, wrapper, or labeling of any device package in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer; or

(B) initiation of specifications for devices that are manufactured by a second party for subsequent commercial distribution by the person initiating specifications.

(18) **[(17)]** Manufacturer - A person who manufactures, fabricates, assembles, or processes a

finished device. The term includes a person who repackages or relabels a finished device. The term does not include a person who only distributes a finished device.

(19) **[(18)]** Misbranded Device - Has the meaning specified in the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431, '431.112.

(20) **[(19)]** Person - Includes individual, partnership, corporation, and association.

(21) **[(20)]** Place of business - Each location at which a device is manufactured or held for distribution.

(22) Practitioner - Means a person licensed by the Texas State Board of Medical Examiners, State Board of Dental Examiners, Texas State Board of Podiatric Medical Examiners, Texas Optometry Board, or State Board of Veterinary Medical Examiners to prescribe and administer prescription devices.

(23) Prescription device - A restricted device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which

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adequate directions for use cannot be prepared.

(24) **[(21)]** Radiation machine - Any device capable of producing ionizing radiation except those devices with radioactive material as the only source of radiation.

(25) **[(22)]** Radioactive material - Any material (solid, liquid, or gas) that emits radiation spontaneously.

(26) **[(23)]** Reconditioning - Any appropriate process or procedure by which distressed merchandise can be brought into compliance with departmental standards as specified in the Texas Food, Drug, Device, and Cosmetic Salvage Act, Health and Safety Code, Chapter 432, '432.003, as interpreted in the rules of the board in '229.192 of this title (relating to Definitions).

(27) **[(24)]** Restricted device - A device subject to certain controls related to sale, distribution, or use as specified in the Federal Food, Drug, and Cosmetic Act, as amended, '520(e)(1).

'229.434. Exemptions.

(a) (No change.)

(b) An exemption from the licensing requirements under these sections does not constitute

an exemption from other applicable provisions of the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431; the Texas Dangerous Drug Act, Health and Safety Code, Chapter 483; **[(Act)]** or the rules adopted **[by the Texas Board of Health]** to administer and enforce the Acts **[Act]**.

'229.435. Licensure Requirements.

(a) - (i) (No change.)

(j) Amendment of license. A license that is amended, including a change of name, ownership, or a notification of a change in the location of a licensed place of business will require submission of an application as outlined in '229.436 of this title (relating to Licensing Procedures) and submission of fees as outlined in '229.439 of this title (relating to Licensure Fees).

(k) (No change.)

(l) Combination products. If the United States Food and Drug Administration determines, with respect to a product that is a combination of a drug and a device, that the primary mode of action of the product is as a device, a distributor or manufacturer of the product is subject to licensure as described in this section.

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'229.436. Licensing Procedures.

(a) License application forms. License application forms may be obtained from the Texas Department of Health, Licensing and Enforcement **[Drugs and Medical Devices]** Division, 1100 West 49th Street, Austin, Texas, 78756 or from the Bureau of Food and Drug Safety website at http://www.tdh.state.tx.us/bfds/lic/apps.html.

(b) Initial license **[License]** application. The initial application for licensure as a device distributor or manufacturer **[license application]** shall be signed and verified, shall be made on a license application form furnished by the Texas Department of Health (department), and shall contain the following information:

(1) - (2) (No change.)

(3) if a proprietorship, the name and residence address of the proprietor; if a partnership, the names and residence addresses of all partners; if a corporation, the date and place of incorporation and name and address of its registered agent in the state and corporation charter number **[a copy of the Articles of Incorporation]**; or if any other type of association, then the names of the principals of such association;

(4) - (7) (No change.)

(c) Renewal license application. The renewal application for licensure as a device distributor or manufacturer shall be made on a license application form furnished by the department.

'229.439. Licensure Fees.

(a) (No change.)

(b) Exemption from licensure fees. A person is exempt from the licensure fees required by this section if the person is:

(1) licensed under '289.252 of this title (relating to Licensing of Radioactive Material) or registered under '289.226 **['289.122]** of this title (relating to Registration of Radiation Machine Use and Services) and engages only in the following types of device distribution or manufacturing:

(A) - (B) (No change.)

(2) (No change.)

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(c) (No change.)

'229.441. Minimum Standards for Licensure.

(a) (No change.)

(b) Federal establishment registration and device listing. All persons who operate as device distributors or manufacturers in Texas shall meet the applicable requirements in 21 Code of Federal Regulations (CFR), Part 807, titled "Establishment Registration and Device Listing for Manufacturers and Initial Importers **[Distributors]** of Devices." Devices distributed by device distributors or manufacturers shall have met, if applicable, the premarket notification requirements of 21 CFR, Part 807 or the premarket approval provisions of 21 CFR, Part 814, titled "Premarket Approval of Medical Devices."

(c) - (h) (No change.)

(i) Medical device reporting. Device distributors or manufacturers shall meet the applicable medical device reporting requirements of 21 CFR, Part 803, titled "Medical Device Reporting" **[or 21 CFR, Part 804, titled "Medical Device Distributor Reporting"]**.

(j) (No change.)

(k) Distribution of prescription devices.

(1) A prescription device in the possession of a device distributor or manufacturer licensed under these sections of this subchapter is exempt from Health and Safety Code, '431.112(f)(1), relating to labeling bearing adequate directions for use, providing it meets the requirements of 21 CFR, ''801.109, titled APrescription devices@ and 801.110, titled ARetail exemption for prescription devices@.

(2) Each device distributor or manufacturer who distributes prescription devices shall maintain a record for every prescription device, showing the identity and quantity received or manufactured and the disposition of each device.

(3) Each device distributor or manufacturer who delivers a prescription device to the ultimate user shall maintain a record of any prescription or other order lawfully issued by a practitioner in connection with the device.

(l) Sale of contact lenses at flea markets. Contact lenses may not be sold by persons at flea markets unless:

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(1) the person selling the contact lenses has complied with the requirements of Business and Commerce Code, '35.55; and

(2) the person selling the contact lenses has complied with the requirements of the Texas Contact Lens Prescription Act, Texas Civil Statutes, Article 4552-A.

'229.443. Enforcement and Penalties.

(a) - (b) (No change.)

(c) Access to records.

(1) A person who is required to maintain records referenced in these sections or under the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 (Act) or '519 or '520(g) of the Federal Food, Drug, and Cosmetic Act or a person who is in charge or custody of those records shall, at the request of an authorized agent or health authority, permit the authorized agent or health authority at all reasonable times access to and to copy and verify the records.

(2) A person who is subject to licensure under these sections of this subchapter shall, at the request of an authorized agent or health authority, permit the authorized agent or health

authority at all reasonable times access to and to copy and verify all records showing:

(A) the movement in commerce of any device;

(B) the holding of any device after movement in commerce; and

(C) the quantity, shipper, and consignee of any device.

(d) Retention of records. Records required by these sections of this subchapter shall be maintained at the place of business or other location that is reasonably accessible for a period of at least 2 years following disposition of the device unless a greater period of time is required by laws and regulations adopted in '229.432 of this title (relating to Applicable Laws and Regulations).

(e) **[(d)]** Adulterated and misbranded device. If the Texas Department of Health (department) identifies an adulterated or misbranded device, the department may impose **[enforce]** the applicable provisions of Subchapter C of the Act including, but not limited to: detention, emergency order, recall, condemnation, destruction, injunction, civil penalties, criminal penalties **[enforcement]**, and/or administrative penalties**.[,]** Administrative and civil penalties will be assessed using the Severity Levels contained **[set out]** in '229.261 of this title (relating to Assessment of Administrative or Civil Penalties).